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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,309	08/27/2001	Virginia Pact Richter	4164-101 CON	5504

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/940,309	Richter et al.
Examiner	**Art Unit**
Phyllis G. Spivack	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 18, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) *15 and 17* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-14, 16, and 18-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

In response to the request for an election of species, Applicants' election of mirtazapine, a compound exhibiting both 5-HT antagonist and α-2 antagonist activities, filed February 18, 2003, Paper No. 7, 2003, is acknowledged. It is noted the structure of 1,2,3,4,10,14b-hexahydro-2-methyl-pyrazino[2,1-a]pyrido[2,3-c]benzazepine is incorrectly drawn in Paper No. 7, as well as in the specification on page 13.

Accordingly, the subject matter presently under consideration are methods of combating movement disorder in a patient experiencing or susceptible to same comprising administering the 5-HT antagonist/α-2 antagonist mirtazapine, claims 1-14, 16 and 18-30. Claims 15 and 17 are withdrawn from consideration by the Examiner, 37 C FR 1.142(b), as being drawn to non-elected inventions.

A Preliminary Amendment filed August 27, 2001, Paper No. 1 ½, and an Information Disclosure Statement filed January 28, 2002, Paper No. 4, are further acknowledged.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C FR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C FR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C FR 3.73(b).

Claims 1-14, 16 and 18-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,281,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

Because the elected species has been allowed in the parent application, the search has been extended according to current Markush practice.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, 26, 27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Henry et al., Experimental Neurology (abstract).

Henry teaches the administration of both an α2-adrenergic receptor antagonist, yohimbine, and the 5-HT uptake inhibitor, 5-MDOT, to combat the movement disorder dyskinesias that are associated with Parkinson's disease.

Claims 1-4, 7, 13, 16, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Rawlow et al., European Journal of Pharmacology (abstract).

Rawlow teaches the administration of both an α2-adrenoceptor antagonist, yohimbine, and the 5-HT receptor antagonist, cyproheptadine, to combat the movement disorder myoclonus.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14, 16 and 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Henry et al., Experimental Neurology (abstract) or Rawlow et al., European Journal of Pharmacology (abstract), in view of Davis et al., CNS Drugs (abstract).

Both Henry and Rawlow teach the administration of an α2 antagonist and a 5-HT antagonist in methods of combating movement disorders. Neither reference discloses mirtazapine as a compound that exhibits both 5-HT antagonism and α2-antagonism. However, Davis teaches

this specific dual activity in mirtazapine, a commercially available drug. Therefore, in view of the combined teachings of the references, one skilled in the art would have been motivated to administer mirtazapine for use in methods of combating movement disorder. Such indication would have been obvious in the absence of evidence to the contrary because compounds that demonstrate 5-HT antagonism and/or α2 antagonism are established in the prior art as effective in combating movement disorders. The determination of optimal dosages of mirtazapine is a parameter well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

June 27, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER